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<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional) 29997/064	
<p><i>facsimile transmittal</i></p> <p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on <u>June 18, 2009</u></p> <p>Signature <u>TPR</u></p> <p>Typed or printed Thomas P. Riley name</p>		<p>Application Number 10/798,614</p> <p>Filed 03/11/2004</p> <p>First Named Inventor Jose Luis Moctezuma de la Barrera</p> <p>Art Unit 3737</p> <p>Examiner Elmer M. Chao</p>	
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p>			
<p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/98)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>50,556</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34</p>		<p><u>TPR</u> Signature Thomas P. Riley Typed or printed name</p> <p><u>312-263-4700</u> Telephone number</p> <p><u>June 18, 2009</u> Date</p>	
<p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>			
<p><input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.</p>			

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IN THE UNITED STATES PATENT  
AND TRADEMARK OFFICERECEIVED  
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JUN 18 2009

Applicants: de la Barrera et al.

Serial No.: 10/798,614

Filed: March 11, 2004

For: System, Device, and Method for  
Determining a Position of an Object

Group Art Unit: 3737

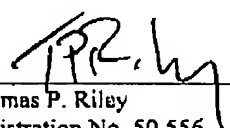
Examiner: Elmer M. Chao

Docket No.: 29997/064

Customer No.: 29471

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June 18, 2009

  
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Attorney for ApplicantsPRE-APPEAL BRIEF REQUEST FOR REVIEWMail Stop AF  
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Sir:

Applicants respectfully request that a pre-appeal brief conference be conducted to review and respond to the following errors in law and fact:

The pending final Office action dated Mach 18, 2009, has made clear legal error by erroneously construing recited means-plus-function elements in claim 39 without referring to the structure disclosed in the specification but rather simply treating the recited elements as recitations of intended function.

Under 35 U.S.C. § 112, ¶6, a claim element recited as "means for" performing a specified function without the recital of structure or material in support thereof "shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." *Id.* In the present application, independent claim 39 recites a device for determining a position and a change in the position of an anatomical structure for use with a surgical navigation system, comprising, *inter alia*, a substrate including means for removably attaching the substrate to an outer

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surface of a body, wherein the body includes an anatomical structure. (Emphasis added.) Independent claim 56 recites, *inter alia*, that the positional device includes a magnetic transmitter attached to the substrate and a magnetic sensor comprising means for attachment to the anatomical structure. (Emphasis added.) In both claims 39 and 56, the recitations of "means for" immediately followed by recitations of the intended functions of either "attaching the substrate to an outer surface of a body" or "attachment to the anatomical structure" are clearly means-plus-function claim elements that must be construed by the examiner in accordance with 35 U.S.C. § 112, ¶ 6. The specification of the present application discloses examples of structures that are described as performing the function of removably attaching the substrate to an outer surface of an anatomical structure. For example, the specification states that, "The substrate 106 may be mounted to the outer surface 111 of the body 112 by an adhesive material, a band, or any other suitable attachment means presently used in conventional surgical operations." U.S. Patent Application No. 10/798,614, at ¶ [0034] (as originally filed), last sentence.

The reasons for rejection presented in the pending final Office action, however, clearly do not apply the correct legal standard for either construing these means-plus-function recitations or for considering the patentability of such recitations in view of the applied references. For example, in response to the arguments of Applicants' Response dated August 26, 2008, with respect to independent claim 56, it is stated in the pending Office action that "Bova teaches that the probe is 'held against the patient' (col. 8, lines 6-7), which would fully satisfy the action of 'attaching' and would also inherently require 'a means for attaching' (i.e. an operator's hand)." Pending O.A. at page 3. In other words, in the reasoning of the pending Office action, the operator's hand disclosed in Bova is (erroneously) considered to meet the means-plus-function structural element recited in claim 56. This is clearly not in accordance with the law of how a means-plus-function claim recitation must be construed, examined, and considered when considering the patentability of the attendant claim.

Further, with regard to claim 39, it is stated in the pending Office action that, "Examiner asserts that Acker's magnetic structure would be just as *capable of* attaching to an anatomical structure as it would be a probe. . . . because the means provided that would allow an attachment to

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the probe would certainly also allow attachment to the an anatomical structure.” Pending O.A. at page 3 (emphasis in original). It is further reasoned in the pending Office action that “the recitation [of the means for attachment to the anatomical structure] would be an example of functional language, and can be met with alternative interpretations of Acker’s magnetic structure.” Pending O.A. at page 3. Finally, as yet another alternative reasoning, it is argued in the Office action that “Acker explicitly teaches that the magnetic sensor is capable of being attached to an anatomical structure based on the fact that the sensor is attached to the probe, and the probe is inserted in the patient. . . . Therefore, the sensor is attachable to an anatomical structure by means of the probe.” Pending O.A. at page 4. All of these rationales presented in the Office action, however, again clearly ignore the fact that the recited “means for attaching...” element is a positive recitation of specific structural significance that must be construed and examined in accordance with 35 U.S.C. § 112, ¶ 6. Therefore, the rejections of independent claims 39 and 57 have no basis in law.

In addition, when considered under the correct legal standard, the rejections in the pending Office action are also based on clearly erroneous constructions of fact. In fact, as previously argued by Applicants, neither Bova nor Acker, either singly or in combination, disclose or suggest either the “means for removably attaching the substrate to an outer surface of a body, wherein the body includes an anatomical structure” recited in independent claim 39 or the “means for attachment to the anatomical structure” recited in independent claim 56. Rather, Bova teaches that an ultrasound sensor can be placed against – without attachment to – the body of a patient and held against the patient’s body by the ultrasound operator’s hand. Acker discloses a magnetic sensor attached to a probe, not to a body of a patient. A person of ordinary skill in the art of surgical navigation systems, however, would readily understand that the examples recited in the specification of the present application do not include the hand of the operator, a magnetic attachment mechanism (which would not be magnetically attracted to the body of the patient), or a probe (which is not intended to be attached to a patient at all). The recited claim elements *must* be construed in light of what an ordinary person in the art would understand the words to mean in view of the description in the specification.

Further, the Advisory Office action dated June 12, 2009, does not respond to the arguments

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presented in the applicants' Response After Final Office Action, filed May 18, 2009, and repeated herein with respect to the errors in law. Rather, it is only very briefly suggested in the Advisory Office action that the disclosure of Bova meets the recited means-plus-function recitations because "Bova et al. explicitly teach the indicated substrate 24 can have fasteners for attachment (col. 6, lines 24-33), which would clearly be equivalent to the means listed by paragraph 36 of the instant application." Advisory O.A. at Pg. 2. This newly pointed out rationale, however, is inapposite to the recited claim limitations because the fastener to which the Office action refers is not used or suggested to be used to removably attach the reference device 24 to the patient. Further, absolutely no rationale is provided in the Advisory Office action to support the bare allegation that the "fastener" referred to in Bova would be in any way equivalent to the means recited in the claims. In fact, Bova actually states that "device 24 may have fasteners (not shown) or otherwise be fixed to the probe 22." Bova at 6:32-33 (emphasis added). Thus, the fasteners newly referred to in the Advisory O.A. are not the "means for removably attaching the substrate to an outer surface of a body, wherein the body includes an anatomical structure" recited in independent claim 39 or the "means for attachment to the anatomical structure" recited in independent claim 56. Therefore, for these additional reasons, the rejections of independent claims 39 and 56 also have no basis in fact.

For at least these reasons, the rejections of independent claims 39 and 56 are based on reasoning that is clearly contrary to law and clear factual deficiencies and should be withdrawn. Therefore, independent claims 39 and 56, and claims 40-42, 45, 46, 57-60, 63, 77-79, 84, 87, and 89-95 dependent variously thereon, are in position for allowance, notice of which is requested.

Respectfully submitted,

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June 18, 2009

By: 

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